K040576 JUL 01 2004

1.2 510(k) SUMMARY of Safety & Effectiveness

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Date Prepared: 1 March 2004

Classification Reference: 21 CFR 868.2375

Product Code: MNR – Ventilatory Effort Recorder

Device Class: Class II

Common/Usual Name: Ventilatory Effort Recorder

Proprietary Name: microMESAM® Basic-Set

Predicate Device: Aplab™ (K030379)

Distribution: the product will be marketed in the USA by ResMed Corp.

Intended Use:
The microMESAM® Basic-Set is used for recording the patient's respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.

Device Description:
The MicroMESAM® Basic-Set consists of:

Number of	Type	Article No.:
1	Reusable microMESAM® recorder	161800
50	Disposable nasal pressure cannula and microMESAM® patient's instruction manuals	1619
1	microMESAM® installation CD	167340
1	System instruction manual for specialist medical personnel	561761
2	Batteries 1,5V Mignon	85030
1	Reusable belt for attaching the microMESAM® recorder	629050
1	USB cable	629051
1	Carrying bag	530002
10	Luer-lock caps	626027

The microMESAM® recorder is a single channel battery-powered respiratory pressure sensor system and provides recordings of respiratory pressure during sleep. The physician prescribed device will help to recognise sleep-related respiratory disorders and lead to comprehensive clinical diagnosis and therapy. The patient may actually perform the recording at home by himself. The microMESAM® recorder must be fastened with the re-usable belt on the patient's chest. All relevant respiratory information during sleep will be collected via nasal pressure cannula. The disposable plastic nasal pressure cannula is connected to the microMESAM® recorder and fixed at the patient's nose. After recording, the microMESAM® recorder must be returned to the physician. With the microMESAM® software installed on a personnel computer the physician has the possibility to generate a report with the recorded and analysed data.

Device Technological Characteristics and Comparison to Predicate Device:
The comparison table below, is provided, to demonstrate that the microMESAM® Basic-Set has no significant differences from the predicate device that would adversely affect product safety and effectiveness.

Comparison Parameter	**Sector Medical Corp. ApLab™**	**microMESAM® Basic-Set**
Intended Use	ApLab™ is intended for use in recording respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.	The microMESAM® Basic-Set is used for recording patient's respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.
Intended Environment	recording – at-home analysing – Sector Medical, physician's practice, sleep clinic	recording – at-home analysing – physician's practice, sleep clinic
Population	2 yrs or older	adults
Power Source recorder	3-Volt Lithium battery	2 x batteries: LR6 / Mignon / AA / 1.5V / at least 1.9 Ah or 2 x NiMh accumulators: Mignon / AA / 1.2V / at least 1.9 Ah
Number of channels	Single channel	Single channel
Method of connection to the Patient	Plastic tubing and cannula for pressure sensing; elastic cloth material belt to support unit. The device is to be attached to a patient's arm.	Plastic tubing and cannula for pressure sensing; elastic cloth material belt to support unit. The device is to be attached to a patient's chest.

Safety Characteristics	Use non-conducting, disposable, plastic cannula.	Use non-conducting, disposable, plastic cannula.
Re-use	Plastic cannula is single use disposable. Remaining portions require cleaning	Plastic cannula is single use disposable. Remaining portions require cleaning
Sensor Technology	Utilizes solid-state pressure sensor that converts pressure changes to electrical signal levels	Utilizes solid-state pressure sensor that converts pressure changes to electrical signal levels.
Analysing the recorded data	The recorded data may be downloaded into the ApLab™ software through an USB 1.1 connector plugged into the device. Afterwards the recorded data are automatically analysed and a report can be generated.	The recorded data may be downloaded into the microMESAM® software through an USB 1.1 connector plugged into the device. Afterwards the recorded data are automatically analysed and a report can be generated.

Performance data:
The microMESAM® Basic-Set complies with the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60068-2-1/ and the following
- IEC 10993-1

Clinical tests:
Introduction: Polysomnography (PSG) is considered the gold standard in the diagnosis of sleep disordered breathing (SDB). Because of costs and labor-intensity it is, however, performed last in graded diagnostic protocols that often involve respiratory pressure measurements via nasal pressure cannula as an alternative sensitive method for DSB detection. MicroMESAM, a newly developed screening device based on this method, allows automated analysis of apnoeas, hypopnoeas, flow limitations and snoring.

Aim and Methods: To validate the device, we first compared signal quality of MicroMESAM flow-time curves with those generated by a pneumotachograph. Then, in 50 patients suspected of having obstructive sleep apnoea, we compared MicroMESAM-generated automated analysis with manually scored results of simultaneously collected PSG data.

Results: MicroMESAM-generated flow-time curves corresponded with pneumotachograph-generated curves in 95% of respiratory events, resulting in less 4±2% difference in respective area under the curves. MicroMESAM and PSG generated numbers of apnoeas (r=0.99) and hypopnoea (r=0.81), as well as AHI (r=0.98) correlated highly, displaying mean differences in AHI of 3.8, and in 1.96σ intervall of +11.1 to –3.5/h. Sensitivities and specificities for SDB were 97.3%, respective 46% at SDB-defining AHI of 5, and 100%, respective 87.5%, at SDB-defining AHI of 10.

Summary: MicroMESAM-generated flow-time curves correspond well with pneumotachograph generated curves, producing automated AHIs that are highly sensitive in detecting SDB. MicroMESAM, therefore, is suitable as a screening device for SDB.

Conclusion:

The MicroMESAM® Basic-Set is substantially equivalent to the predicate SECTOR Medical Corp. ApLabTM™. Both Ventilatory Effort Recorders have the same intended use. Based on verification and validation testing completed on the microMESAM® Basic-Set we conclude that the differences do not affect safety and effectiveness of the MicroMESAM® Basic-Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 1 2004

Map Medizintechnik Fur Arzt Und Patient GMBH
C/O Mr. David D' Cruz
Vice President
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K040576
Trade/Device Name: microMESAM Basic-Set
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: June 3, 2004
Received: June 7, 2004

Dear Mr. D' Cruz

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

microMESAM® Basic-Set is used for recording the patient's respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.

Prescription Use _____ yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ no (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040576